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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,059	12/29/2000	James R. Baker JR.	UM-04491	8985

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01/22/2008

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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01/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/751,059	Applicant(s) BAKER ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 186-194, 197 and 199-203 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 186-194, 197 and 199-203 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Examiner acknowledges receipt of power of attorney filed 9/19/07; request for continued examination under 37 CFR 1.114, amendment and remarks filed 10/12/07. Claims 186-190 and 199 are amended. Claims 195, 196 and 198 are canceled. New claims 200-203 are added. Claims 186-194, 197 and 199-203 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/12/2007 has been entered.

Response to Arguments

Previous rejections that are not reiterated herein have been withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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4. Claims 186-194, 197 and 199-203 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

The claims recite 3-15% ethanol and 3-15% surfactant and 0.5-2% cetylpyridinium chloride. The specification as originally filed does not envision the use of ethanol, surfactant and cetylpyridinium chloride in the amounts recited and applicant has not specifically pointed to the specification where these amounts derive support.

Applicant may overcome this rejection by removing the new matter or point to the original specification for support.

5. Claims 186-199 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what "surface of a human" means in the context of the claims.

Response to Arguments

6. Applicant's arguments filed 10/12/07 have been fully considered but they are not persuasive.

Applicant argues the specification at page 17, lines 28 and 29, page 18, lines 1 and 2 and 25-30 and page 19, lines 1-3 define what the surface of a human is.

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This is not found persuasive, because page 17, lines 28 and 29 and page 18, lines 1 and 2 says: "*As used herein, the term "topically" refers to application of the compositions of the present invention to the **surface of the skin and mucosal cells and tissues** (e.g., alveolar, buccal, lingual, masticatory, or nasal mucosa, and other tissues and cells which line hollow organs or body cavities).* Furthermore, page 18, lines 25-30 and page 19, lines 1-3 state as follows: "As used herein, the term "surface" is used in its broadest sense. In one sense, the term refers to the outermost boundaries of an organism or inanimate object (e.g., vehicles, buildings, and food processing equipment, etc.) that are capable of being contacted by the compositions of the present invention (e.g., for animals: the skin, hair, and fur, etc., and for plants: the leaves, stems, flowering parts, and fruiting bodies, etc.). In another sense, the term also refers to the inner membranes and surfaces of animals and plants (e.g., for animals: the digestive tract, vascular tissues, and the like, and for plants: the vascular tissues, etc.) capable of being contacted by compositions by any of a number of transdermal delivery routes (e.g., injection, ingestion, transdermal delivery, inhalation, and the like).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 186-194, 197 and 199-203 are rejected under 35 U.S.C. 103(a) as being unpatentable over Libin (US 5,855,872) in view of Stroud et al. (US 6,231,837).

Libin discloses method of treating diseased tissues that results from herpes simplex virus infection, by applying an oil in water emulsion that contains cetylpyridinium chloride, sterol alcohol, emulsifying agent and mineral oil (abstract; column 1, lines 42, 47-55; column 2, lines 26-64; column 3, line 25 to column 4 line 29) without specifically mentioning a human while disclosing topical application. Stroud teaches an oil in water emulsion (column 17, lines 51 and 52; column 18, lines 6 and 7; column 22, line 14) that is a self tanning composition (column 7, lines 28,29; column 11, line 26; column 12, lines 29 and 30) that contains glycerol (column 7, lines 39 and 40; column 15, lines 41 and 42), ethanol (column 11, line 41), antimicrobial or antifungal agents (column 18, lines 43-46), preservatives or chelating agent such as EDTA helps maintain the ionic strength of the composition(column 19, lines 26, and 54-59), antiviral agent for treating herpes simplex or herpes zoster or chickenpox (column 21, lines 7-9), emollients such as castor oil or soybean oil (column 21, lines 29-32) and surfactant such as polysorbate 20 (column 24, lines 30, 50 and 51), which is TWEEN 20; the oil in water emulsion of Stroud is

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formulated as cream, lotion or ointment (column 17, lines 31, 32). Stroud teaches that the self-tanning formulations are approved for use with humans (column 2, lines 61 and 65). Regarding the %amounts of ethanol, surfactant and % volume oil, the ordinary skilled artisan has within his or her technical grasp to use amounts of oil, surfactant and ethanol desired in the composition that would be effective to treat herpes simplex virus. Both compositions have utility in the treatment of herpes simplex virus via topical route so that a combination of the compositions of Stroud and Libin will yield a composition that would be effective in treating herpes simplex virus. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the composition of Stroud and Libin with the motivation that topically applying the composition to affected areas of a person in need thereof, and specifically to humans in view of Stroud, would treat the affected areas of herpes simplex. Treating the virus results from inactivating the virus and thus leads to decontaminating the affected area.

The application to human the combined composition that contains alcohol, surfactant, oil and the cetylpyridinium chloride meets claims 186-188, 197, 200, 202 and 203. The presence of the ETDA meets claims 189, 190 and 201. The presence of oil or soybean oil meets claims 191 and 192. Polysorbate 20, which is TWEEN 20 meets claims 193 and 194. Ethanol present in the formulation meets claims 186, 200 and 202. The topical application of the formulation in the form of ointment or lotion or cream meets claims 186, 199, 200 and 202.

10. Claims 186-188, 191, 193, 194 and 197-200, 202 and 203 are rejected under 35 U.S.C. 103(a) as unpatentable over Asculai et al. (US 4,020,183) in view of Keith et al. (US 4,350,707).

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Asculai discloses inactivating herpes simplex virus in humans by applying to the infected area an effective amount of oil-in-water emulsion that contains surfactants such as polysorbate 20, which is TWEEN 20 (column 1, line 61; Table 1), halogen containing compound such as cetylpyridinium chloride or benzalkonium chloride (column 1, lines 16 and 17), mineral oil of petrolatum (column 2, lines 48 and 49), alcohols (line 41), the formulation is in the form of cream or lotion (column 2, line 46). Asculai describes method of inactivating the herpes simplex virus in humans by applying the composition to the affected areas (claims 1-6) and while Asculai does not use the term decontamination, inactivation naturally leads to decontamination so that Asculai inherently decontaminates surfaces of the human. Asculai uses surfactant in amounts of between 0.5% and 20%. The composition of Asculai does not contain ethanol as now recited in claims 186, new claims 200 and 202. But Keith uses ethanol containing composition to topically treat herpes simplex virus. Therefore, given the teachings of Asculai and Keith, one of ordinary skill in the art at the time the invention was made would have reasonable expectation of success to inactivate or treat surfaces having the herpes simplex virus with the composition of Asculai to which has been ethanol. While the %ethanol used in Keith is higher than that recited, the mere fact a range is claimed indicates that the amount of the ethanol can be optimized to produce the composition effective to treat the surface of virus.

Response to Arguments

11. A) Applicant's arguments as it relates to the rejection under 35 USC 102(b) as being anticipated by Asculai is moot in view of the amendment to the claims such that the Asculai art is no longer a 102 art. B) Secondly, the amendment to the claims gave rise to new rejections under 35 USC 103 in which the claims are rendered obvious by Asculai in view of Keith. C)

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Applicant did not provide arguments against the rejection of the claims under 35 USC 103 as being unpatentable over Libin (US 5,855,872) in view of Stroud et al. (US 6,231,837).

Therefore, responses to the arguments that are now moot are not provided.

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

